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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,276	09/01/2000	Smadar Cohen	9124.117US01	5848

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EXAMINER
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WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/654,276

Applicant(s)

COHEN ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,9,10 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5,6,9,10,18 and 22 is/are allowed.
- 6) ☒ Claim(s) 16-17, 19-21, and 23-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and response received on 11/29/05 has been entered. Claims 1-3, 5-6, 9-10, and 16-24 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in the instant action can be found in the previous office action.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 16-17, 19-21, 23, and 24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,099,832 (8/8/00), hereafter referred to as Mickle et al., in view of WO 97/44070 (11/27/97), hereafter referred to as Shapiro et al., is maintained. Please note that the rejection is withdrawn over claim 18 as applicants rightly pointed out that claim 18 depends on claim 2, a claim previously indicated as allowable.

Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the rejection of record does not meet one or more of the criteria for establishing a *prima facie* case of obviousness. The applicant states that the claims now recite that the matrix is non-adhesive, and argue that because alginates were known to be non-adhesive,

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citing Rowley et al., the skilled artisan would not have had a reasonable expectation of success in substituting alginate scaffolds for the adhesive collagen scaffolds of Mickle et al.

In response, it is first noted that the Rowley et al. reference had not been provided by the applicants for consideration by the examiner. Although the response on page 5 states that a copy of Rowley et al. was attached to the applicant's response, the transmittal letter indicates that only 8 pages were faxed to the office, 1 page for the transmittal letter, 1 page for the extension of time, and 6 pages of amendments/responses. Therefore, the teachings of Rowley et al. have not been considered.

Further, applicant's amendment of the claims to recite that the matrix is non-adhesive does not overcome the rejection of record. The applicant's arguments clearly state that alginate matrices are non-adhesive, therefore this limitation is clearly taught by the rejection of record which teaches using alginate matrices, see Shapiro et al.

In addition, applicant's arguments that the skilled artisan would not substitute alginate matrices for collagen matrices because of the different cell adherence properties of alginate matrices versus collagen matrices is not persuasive because the rejection of record clearly provides sufficient motivation for making just such a substitution. The rejection of record states that Mickle et al. differs from the instant invention by teaching the use of biodegradable scaffolds made of collagen rather than alginate polysaccharides. Shapiro et al. supplements Mickle et al. by teaching the use of alginate polysaccharide as scaffolds for cells biografts (Shapiro et al., page 5). Specifically, Shapiro et al. teaches methods of making a biodegradable graft where the cells are grown *in vitro* on or within the alginate polysaccharide matrix until they reach a desired state of differentiation (Shapiro et al., paragraph 2). Shapiro et al. *further*

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*provides motivation for using the alginate polysaccharide matrix over other biodegradable matrixes, such as collagen, by teaching that collagen-based matrices have several disadvantages including the contraction of the collagen scaffold during in vitro culture which makes this scaffold unsuitable for prolonged in vitro cultivation of cells, and a rapid rate of degradation in vivo (Shapiro et al., page 3). Shapiro et al. states that because of the drawbacks of using collagen in matrixes, polysaccharide polymer scaffolds are preferred because they support the growth of thick layers of cells and are capable of maintaining the cells in an active functional state in vitro and in vivo, and are further amendable to vascularization (Shapiro et al., page 5).*

Therefore, in view of the substantial benefits to using alginate scaffolds over collagen scaffolds taught by Shapiro et al., it would have been *prima facie* obvious to the skilled artisan to substitute the alginate scaffolds containing controlled release microcapsules containing growth factors taught by Shapiro et al. for the collagen scaffolds containing soluble growth factors taught by Mickle et al. in the methods of making a cardiac biograft taught by Mickle et al. Further, based on the successful growth of cells in the alginate matrix taught by Shapiro et al., the skilled artisan would have had a reasonable expectation of success in making an alginate polysaccharide matrix containing autologous or allogeneic cardiomyocytes which further comprises controlled release polymeric microspheres capable of releasing soluble angiogenic factors.

Therefore, for the reasons discussed in detail above, the rejection of record is maintained over claims 16-17, 19-21, 23, and 24.

Applicant's amendment has necessitated the following new grounds of rejection of the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17, 19-21, and 23-24 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. See *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981) and MPEP 706.03(o) and 2163.06.

The applicant has amended independent claims 16 and 19 to recite that the polysaccharide matrix is “non-adhesive”. Claims 17, 20-21, and 23-24 depend on claim 16 and 19. The applicant's response states that the amendment has added no new matter. However, the response does not point to any particular support in the specification for the newly added limitation to the claims. A review of the specification as filed further does not seem to support this added limitation. The specification only refers to porous polysaccharide matrices, a broad genus of materials which includes the disclosed preferred embodiment of alginate scaffolds. The specification does not teach that all polysaccharide matrices are “non-adhesive” or provide guidance that only “non-adhesive” porous polysaccharide matrices should be used in the

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methods and biografts as claimed. As such, the specification as filed does not provide adequate support for the newly added limitation of “non-adhesive” porous polysaccharide matrices. It is suggested that applicant remove this added limitation to overcome the instant grounds of rejection or specifically point out where in the specification support for this new limitation can be found.

***Allowable Subject Matter***

Claims 1-3, 5-6, 9-10, 18, and 22 are considered free of the prior art for reasons of record as discussed in previous office action and are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER